UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF COMPLIANCE

FIFRA GLP INSPECTION REPORT

Smithers Viscient
Wareham, Massachusetts

April 30 – May 2, 2013

Daniel M. Myers

OFFICE OF COMPLIANCE, GLP PROGRAM
Denver, Colorado

REPORT OF A GLP COMPLIANCE INSPECTION CONDUCTED PURSUANT TO THE FIFRA GLP REGULATIONS

LABORATORY:	Smithers Viscient 790 Main Street Wareham, MA 02571
INVESTIGATION ID:	20133088181
RESPONSIBLE OFFICIAL:	Volker Bornemann, Ph.D. President Phone: (508) 295-2550
DATES OF INSPECTION:	April 30 – May 2, 2013

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SUMMARY

A FIFRA GLP inspection was conducted at Smithers Viscient in Wareham, MA, on April 30 – May 2, 2013. Three study audits were accomplished in addition to a GLP compliance review. The GLP compliance review was conducted using one in-progress study selected from the facility's master schedule. Findings for the GLP compliance review and the study audits are summarized below.

- Some SOPs used by lab personnel were "originated" by a member of the QAU.

I. INTRODUCTION

A FIFRA Good Laboratory Practice (GLP) Standards compliance inspection was conducted at Smithers Viscient on April 30 – May 2, 2013. Dr. Kirk Smith, Sr. Director, Quality Systems and Regulatory Affairs of Smithers Viscient, was notified of the pending inspection via letter [Exhibit 1] from Ms. Francisca E. Liem, Director EPA's GLP Program. The letter identified the inspection team, the studies to be audited and the data and records to be made available.

The week prior to the inspection, Dr. Smith was contacted by the lead inspector, Daniel M. Myers, from the EPA / Office of Compliance, GLP Program, via telephone to discuss the upcoming inspection logistics. Mr. Myers explained that the inspection team would conduct a FIFRA GLP inspection involving three study audits and a GLP compliance review.

The inspection team consisted of Mr. Myers who conducted the study audits and the GLP compliance inspection.

II. OPENING CONFERENCE

An opening conference was held beginning at approximately 9:10 a.m. on Tuesday, April 30, 2013. The inspection was led by Mr. Daniel M. Myers, Chemist, from EPA, GLP Program.

Official credentials were presented to Smithers Viscient officials upon entry. A FIFRA Notice of Inspection [Exhibit 2] was presented to and signed by Dr. Volker Bornemann, President of Smithers Viscient.

Facility employee present at this opening conference include; Dr. Smith, Dr. Bornemann, Susan Shepherd, Vice President, Dr. Paul Reibach, Director of Chemistry Services, Dr. Kalumbu Malekani, Director Environmental Fate and Metabolism, and Eric Steele, Manager of Quality Assurance. Mr. Steele gave a presentation summary of Smithers Viscient's history including the scope of their operations and the extent of GLP involvement. Additional details for the conduct of the inspection were discussed and an inspection schedule was agreed upon.

III. HISTORY OF THE FACILITY

Smithers Viscient is a contract research organization providing GLP research programs focusing on Aquatic Eco Toxicology, Environmental Fate / Metabolism and Analytical Chemistry.

This Facility was started in 1969 at its current location in Wareham, MA. Facility officials estimate that approximately 90% of the work conducted at Smithers Viscient is regulated by the GLP standards for data submissions to both the EPA and the FDA.

Smithers Viscient employs approximately 145 people. The facility contains approximately 57,000 ft^2 of space which includes offices, archives and laboratories.

More information can be found at www.smithersviscient.com.

IV. EXIT CONFERENCE

The exit conference was held on Thursday, May 2, 2013 by Mr. Myers, to review findings and recommendations of the GLP standards inspection and data audits. A list of Smithers Viscient employees present at this Exit Conference is included in Exhibit 5. An Inspection Observations form [Exhibit 3] was completed and copied for Dr. Bornemann, providing written indication of findings discussed in the closing conference. A FIFRA Receipt for Samples [Exhibit 4] was provided to Dr. Bornemann for all documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	Notification Letter	(3 pages)
Exhibit 2	FIFRA Notice of Inspection	
Exhibit 3	Inspection Observations Form	
Exhibit 4	FIFRA Receipt for Samples	
Exhibit 5	Closing Conference Sign-in Sheet	

VI. SIGNATURE:

Inspector: Name: Daniel M. Myers
Affiliation: EPA, Office of Compliance, GLP Program

Daniel M. Myers — 5/30/2013
Daniel M. Myers — Date

APPENDIX A

REPORT OF GLP COMPLIANCE REVIEW

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Review:	April 30 – May 2, 2013

I. Summary of Findings

A FIFRA GLP inspection was conducted at Smithers Viscient located in Wareham, Massachusetts, on April 30 – May 2, 2013. A GLP compliance review was conducted using one on-going study selected from the facility master schedule. Findings for the compliance review are summarized below.

- Some SOPs used by lab personnel were "originated" by a member of the QAU. This may not demonstrate a clear separation between QA and personnel engaged in the direction and conduct of the study required by the GLP regulations.

II. Findings from Previous GLP Compliance Review

The previous FIFRA GLP inspection was conducted at this facility in 2010. No significant adverse findings were noted during that inspection

III. Ongoing Study

The following study was selected from the master schedule to serve as partial basis for the GLP compliance review:

Test Substance:	Acetone
Study Title:	Protocol for Conducting a Short – Term Reproduction Assay with Fathead Minnow (*Pimephales promelas*) Following OPPTS 890.1350 and OECD 229 Guidelines
Study No.:	14036.6106
Sponsor:	American Chemistry Council 700 2nd Street, NE Washington, DC 20002
Study Director:	Duncan York Smithers Viscient
Study Initiation Date:	June 6, 2012

Proposed Experimental Termination Date: October 17, 2012

IV. Findings from Current GLP Compliance Review

The GLP standards compliance review was conducted through interviews with Smithers Viscient personnel and tours of laboratories, animal rooms, archives and chemical storage areas. Personnel *curricula vitae* and training records were reviewed, as well as SOPs, organization charts, instrument maintenance logs, and test and reference substance receipt and distribution, and written procedures for the Quality Assurance Unit.

The following describe any findings and recommendations:

- Some SOPs used by lab personnel were "originated" by a member of the QAU. This may not demonstrate a clear separation between QA and personnel engaged in the direction and conduct of the study required by the GLP regulations.

  Citation: 40 CFR §160.35(a)

  Evidence Collected: SOP 09.001.03 [Exhibit A-2]
  Organization chart [Exhibit A-3]

  Laboratory Response: The facility responded in a letter to Daniel M. Myers, dated May 24, 2013 [Exhibit A-4]

Persons Interviewed:

Name	Title
Dr. Kirk Smith	Sr. Director, Quality Systems and Regulatory Affairs
Eric Steele	Manager, Quality Assurance

V. LIST OF EXHIBITS

Exhibit A-1	Study Protocol	(27 pages)
Exhibit A-2	SOP 09.001.03	(9 pages)
Exhibit A-3	Organization Chart	(9 pages)
Exhibit A-4	Facility response letter	(2 pages)

VI. SIGNATURE:

Inspector: Name: Daniel M. Myers
Affiliation: EPA, Office of Compliance, GLP Program

Daniel M. Myers — 5/30/2013
Daniel M. Myers — Date

Appendix B

STUDY AUDIT REPORT

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Audit:	April 30 – May 2, 2013
Test Substance:	Phosment
Study Title:	Phosmet – Amphibian Metamorphosis Assay with African Clawed Frog (*Xenopus laevis*) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline No. 231
Study No.:	12791.6142
EPA MRID No.:	48673001
Sponsor:	Gowan Company 370 South Main Street Yuma, AZ 85364
Study Director:	Michael Lee Smithers Viscient
Study Start Date:	July 11, 2011
Study Completion Date:	February 27, 2012
Inspector:	Daniel M. Myers U.S. EPA Office of Compliance, GLP Program

THIS REPORT PERTAINS TO THE AUDIT OF THE FOLLOWING ASPECTS OF THE STUDY:

AMPHIBIAN METAMORPHOSIS ASSY – APPENDIX B

I. SUMMARY OF AUDIT FINDINGS

This study was conducted after the effective date of the FIFRA GLP Standards regulations, 40 CFR Part 160 [Exhibit B-1]. The study report contained a GLP compliance statement signed by the sponsor, submitter and study director as required by § 160.12 [Exhibit B-1].

- No observed adverse findings.

II. CONDUCT OF THE AUDIT

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements and appropriate SOPs and the study protocol.

The following aspects of the study were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt and distribution and administration and chemical characterization.

Any issues were discussed with facility personnel, during the course of the inspection and/or during the exit conference.

III. STUDY AUDIT FINDINGS

- No observed adverse findings.

IV. EXHIBITS

Exhibit B-1 Final study report information pages including the Protocol cover page (5 pages)

V. INSPECTOR

Name: Daniel Myers
Affiliation: U.S. EPA Office of Compliance
GLP Program

Daniel Myers

5/30/2013
Date

Appendix C

STUDY AUDIT REPORT

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Audit:	April 30 – May 2, 2013
Test Substance:	Pyriproxyfen
Study Title:	Pyriproxyfen – Amphibian Metamorphosis Assay with African Clawed Frog (*Xenopus laevis*) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline No. 231
Study No.:	13048.6672
EPA MRID No.:	48619201
Sponsor:	Valent U.S.A. Corporation P.O. Box 8025 1600 Riviera Ave, Suite 200 Walnut Creek, CA 94596
Study Director:	Michael Lee Smithers Viscient
Study Start Date:	September 20, 2010
Study Completion Date:	January 25, 2012
Inspector:	Daniel M. Myers U.S. EPA Office of Compliance, GLP Program

THIS REPORT PERTAINS TO THE AUDIT OF THE FOLLOWING ASPECTS OF THE STUDY:

AMPHIBIAN METAMORPHOSIS ASSY – APPENDIX C

I. SUMMARY OF AUDIT FINDINGS

This study was conducted after the effective date of the FIFRA GLP Standards regulations, 40 CFR Part 160 [Exhibit C-1]. The study report contained a GLP compliance statement signed by the sponsor, submitter and study director as required by § 160.12 [Exhibit C-1].

- No observed adverse findings.

II. CONDUCT OF THE AUDIT

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements and appropriate SOPs and the study protocol.

The following aspects of the study were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt and distribution and administration and chemical characterization.

Any issues were discussed with facility personnel, during the course of the inspection and/or during the exit conference.

III. STUDY AUDIT FINDINGS

- No observed adverse findings.

IV. EXHIBITS

Exhibit C-1 Final study report information pages including the Protocol cover page (5 pages)

V. INSPECTOR

Name: Daniel Myers
Affiliation: U.S. EPA Office of Compliance
GLP Program

Daniel Myers

5/30/2013
Date

Appendix D

STUDY AUDIT REPORT

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Audit:	April 30 – May 2, 2013
Test Substance:	Iprodione
Study Title:	Iprodione – Amphibian Metamorphosis Assay with African Clawed Frog (*Xenopus laevis*) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline No. 231
Study No.:	13798.6271
EPA MRID No.:	48671501
Sponsor:	Bayer CropScience 2 T.W. Alexander Drive RTP, NC 27709
Study Director:	Michael Lee Smithers Viscient
Study Start Date:	May 18, 2011
Study Completion Date:	March 28, 2012
Inspector:	Daniel M. Myers U.S. EPA Office of Compliance, GLP Program

THIS REPORT PERTAINS TO THE AUDIT OF THE FOLLOWING ASPECTS OF THE STUDY:

AMPHIBIAN METAMORPHOSIS ASSY – APPENDIX D

I. SUMMARY OF AUDIT FINDINGS

This study was conducted after the effective date of the FIFRA GLP Standards regulations, 40 CFR Part 160 [Exhibit D-1]. The study report contained a GLP compliance statement signed by the sponsor, submitter and study director as required by § 160.12 [Exhibit D-1].

- No observed adverse findings.

II. CONDUCT OF THE AUDIT

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements and appropriate SOPs and the study protocol.

The following aspects of the study were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt and distribution and administration and chemical characterization.

Any issues were discussed with facility personnel, during the course of the inspection and/or during the exit conference.

III. STUDY AUDIT FINDINGS

- No observed adverse findings.

IV. EXHIBITS

Exhibit D-1 Final study report information pages including the Protocol cover page (5 pages)

V. INSPECTOR

Name: Daniel Myers
Affiliation: U.S. EPA Office of Compliance
GLP Program

Daniel Myers

5/30/2013
Date

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF COMPLIANCE

FIFRA GLP INSPECTION REPORT

Smithers Viscient
Wareham, Massachusetts

April 30 – May 2, 2013

Daniel M. Myers

OFFICE OF COMPLIANCE, GLP PROGRAM
Denver, Colorado

REPORT OF A GLP COMPLIANCE INSPECTION CONDUCTED PURSUANT TO THE FIFRA GLP REGULATIONS

LABORATORY:	Smithers Viscient 790 Main Street Wareham, MA 02571
INVESTIGATION ID:	20133088181
RESPONSIBLE OFFICIAL:	Volker Bornemann, Ph.D. President Phone: (508) 295-2550
DATES OF INSPECTION:	April 30 – May 2, 2013

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- Some SOPs used by lab personnel were "originated" by a member of the QAU.

I. INTRODUCTION

A FIFRA Good Laboratory Practice (GLP) Standards compliance inspection was conducted at Smithers Viscient on April 30 – May 2, 2013. Dr. Kirk Smith, Sr. Director, Quality Systems and Regulatory Affairs of Smithers Viscient, was notified of the pending inspection via letter [Exhibit 1] from Ms. Francisca E. Liem, Director EPA's GLP Program. The letter identified the inspection team, the studies to be audited and the data and records to be made available.

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The inspection team consisted of Mr. Myers who conducted the study audits and the GLP compliance inspection.

II. OPENING CONFERENCE

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Official credentials were presented to Smithers Viscient officials upon entry. A FIFRA Notice of Inspection [Exhibit 2] was presented to and signed by Dr. Volker Bornemann, President of Smithers Viscient.

Facility employee present at this opening conference include; Dr. Smith, Dr. Bornemann, Susan Shepherd, Vice President, Dr. Paul Reibach, Director of Chemistry Services, Dr. Kalumbu Malekani, Director Environmental Fate and Metabolism, and Eric Steele, Manager of Quality Assurance. Mr. Steele gave a presentation summary of Smithers Viscient's history including the scope of their operations and the extent of GLP involvement. Additional details for the conduct of the inspection were discussed and an inspection schedule was agreed upon.

III. HISTORY OF THE FACILITY

Smithers Viscient is a contract research organization providing GLP research programs focusing on Aquatic Eco Toxicology, Environmental Fate / Metabolism and Analytical Chemistry.

This Facility was started in 1969 at its current location in Wareham, MA. Facility officials estimate that approximately 90% of the work conducted at Smithers Viscient is regulated by the GLP standards for data submissions to both the EPA and the FDA.

Smithers Viscient employs approximately 145 people. The facility contains approximately 57,000 ft^2 of space which includes offices, archives and laboratories.

More information can be found at www.smithersviscient.com.

IV. EXIT CONFERENCE

The exit conference was held on Thursday, May 2, 2013 by Mr. Myers, to review findings and recommendations of the GLP standards inspection and data audits. A list of Smithers Viscient employees present at this Exit Conference is included in Exhibit 5. An Inspection Observations form [Exhibit 3] was completed and copied for Dr. Bornemann, providing written indication of findings discussed in the closing conference. A FIFRA Receipt for Samples [Exhibit 4] was provided to Dr. Bornemann for all documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	Notification Letter	(3 pages)
Exhibit 2	FIFRA Notice of Inspection	
Exhibit 3	Inspection Observations Form	
Exhibit 4	FIFRA Receipt for Samples	
Exhibit 5	Closing Conference Sign-in Sheet	

VI. SIGNATURE:

Inspector: Name: Daniel M. Myers
Affiliation: EPA, Office of Compliance, GLP Program

Daniel M. Myers — 5/30/2013
Daniel M. Myers — Date

APPENDIX A

REPORT OF GLP COMPLIANCE REVIEW

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Review:	April 30 – May 2, 2013

I. Summary of Findings

A FIFRA GLP inspection was conducted at Smithers Viscient located in Wareham, Massachusetts, on April 30 – May 2, 2013. A GLP compliance review was conducted using one on-going study selected from the facility master schedule. Findings for the compliance review are summarized below.

- Some SOPs used by lab personnel were "originated" by a member of the QAU. This may not demonstrate a clear separation between QA and personnel engaged in the direction and conduct of the study required by the GLP regulations.

II. Findings from Previous GLP Compliance Review

The previous FIFRA GLP inspection was conducted at this facility in 2010. No significant adverse findings were noted during that inspection

III. Ongoing Study

The following study was selected from the master schedule to serve as partial basis for the GLP compliance review:

Test Substance:	Acetone
Study Title:	Protocol for Conducting a Short – Term Reproduction Assay with Fathead Minnow (*Pimephales promelas*) Following OPPTS 890.1350 and OECD 229 Guidelines
Study No.:	14036.6106
Sponsor:	American Chemistry Council 700 2nd Street, NE Washington, DC 20002
Study Director:	Duncan York Smithers Viscient
Study Initiation Date:	June 6, 2012

Proposed Experimental Termination Date: October 17, 2012

IV. Findings from Current GLP Compliance Review

The GLP standards compliance review was conducted through interviews with Smithers Viscient personnel and tours of laboratories, animal rooms, archives and chemical storage areas. Personnel *curricula vitae* and training records were reviewed, as well as SOPs, organization charts, instrument maintenance logs, and test and reference substance receipt and distribution, and written procedures for the Quality Assurance Unit.

The following describe any findings and recommendations:

- Some SOPs used by lab personnel were "originated" by a member of the QAU. This may not demonstrate a clear separation between QA and personnel engaged in the direction and conduct of the study required by the GLP regulations.

  Citation: 40 CFR §160.35(a)

  Evidence Collected: SOP 09.001.03 [Exhibit A-2]
  Organization chart [Exhibit A-3]

  Laboratory Response: The facility responded in a letter to Daniel M. Myers, dated May 24, 2013 [Exhibit A-4]

Persons Interviewed:

Name	Title
Dr. Kirk Smith	Sr. Director, Quality Systems and Regulatory Affairs
Eric Steele	Manager, Quality Assurance

V. LIST OF EXHIBITS

Exhibit A-1	Study Protocol	(27 pages)
Exhibit A-2	SOP 09.001.03	(9 pages)
Exhibit A-3	Organization Chart	(9 pages)
Exhibit A-4	Facility response letter	(2 pages)

VI. SIGNATURE:

Inspector: Name: Daniel M. Myers
Affiliation: EPA, Office of Compliance, GLP Program

Daniel M. Myers — 5/30/2013
Daniel M. Myers — Date

Appendix B

STUDY AUDIT REPORT

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Audit:	April 30 – May 2, 2013
Test Substance:	Phosment
Study Title:	Phosmet – Amphibian Metamorphosis Assay with African Clawed Frog (*Xenopus laevis*) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline No. 231
Study No.:	12791.6142
EPA MRID No.:	48673001
Sponsor:	Gowan Company 370 South Main Street Yuma, AZ 85364
Study Director:	Michael Lee Smithers Viscient
Study Start Date:	July 11, 2011
Study Completion Date:	February 27, 2012
Inspector:	Daniel M. Myers U.S. EPA Office of Compliance, GLP Program

THIS REPORT PERTAINS TO THE AUDIT OF THE FOLLOWING ASPECTS OF THE STUDY:

AMPHIBIAN METAMORPHOSIS ASSY – APPENDIX B

I. SUMMARY OF AUDIT FINDINGS

This study was conducted after the effective date of the FIFRA GLP Standards regulations, 40 CFR Part 160 [Exhibit B-1]. The study report contained a GLP compliance statement signed by the sponsor, submitter and study director as required by § 160.12 [Exhibit B-1].

- No observed adverse findings.

II. CONDUCT OF THE AUDIT

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements and appropriate SOPs and the study protocol.

The following aspects of the study were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt and distribution and administration and chemical characterization.

Any issues were discussed with facility personnel, during the course of the inspection and/or during the exit conference.

III. STUDY AUDIT FINDINGS

- No observed adverse findings.

IV. EXHIBITS

Exhibit B-1 Final study report information pages including the Protocol cover page (5 pages)

V. INSPECTOR

Name: Daniel Myers
Affiliation: U.S. EPA Office of Compliance
GLP Program

Daniel Myers

5/30/2013
Date

Appendix C

STUDY AUDIT REPORT

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Audit:	April 30 – May 2, 2013
Test Substance:	Pyriproxyfen
Study Title:	Pyriproxyfen – Amphibian Metamorphosis Assay with African Clawed Frog (*Xenopus laevis*) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline No. 231
Study No.:	13048.6672
EPA MRID No.:	48619201
Sponsor:	Valent U.S.A. Corporation P.O. Box 8025 1600 Riviera Ave, Suite 200 Walnut Creek, CA 94596
Study Director:	Michael Lee Smithers Viscient
Study Start Date:	September 20, 2010
Study Completion Date:	January 25, 2012
Inspector:	Daniel M. Myers U.S. EPA Office of Compliance, GLP Program

THIS REPORT PERTAINS TO THE AUDIT OF THE FOLLOWING ASPECTS OF THE STUDY:

AMPHIBIAN METAMORPHOSIS ASSY – APPENDIX C

I. SUMMARY OF AUDIT FINDINGS

This study was conducted after the effective date of the FIFRA GLP Standards regulations, 40 CFR Part 160 [Exhibit C-1]. The study report contained a GLP compliance statement signed by the sponsor, submitter and study director as required by § 160.12 [Exhibit C-1].

- No observed adverse findings.

II. CONDUCT OF THE AUDIT

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements and appropriate SOPs and the study protocol.

The following aspects of the study were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt and distribution and administration and chemical characterization.

Any issues were discussed with facility personnel, during the course of the inspection and/or during the exit conference.

III. STUDY AUDIT FINDINGS

- No observed adverse findings.

IV. EXHIBITS

Exhibit C-1 Final study report information pages including the Protocol cover page (5 pages)

V. INSPECTOR

Name: Daniel Myers
Affiliation: U.S. EPA Office of Compliance
GLP Program

Daniel Myers

5/30/2013
Date

Appendix D

STUDY AUDIT REPORT

Test Facility:	Smithers Viscient 790 Main Street Wareham, MA 02571
Dates of Audit:	April 30 – May 2, 2013
Test Substance:	Iprodione
Study Title:	Iprodione – Amphibian Metamorphosis Assay with African Clawed Frog (*Xenopus laevis*) Following OPPTS Test Guideline 890.1100 and OECD Test Guideline No. 231
Study No.:	13798.6271
EPA MRID No.:	48671501
Sponsor:	Bayer CropScience 2 T.W. Alexander Drive RTP, NC 27709
Study Director:	Michael Lee Smithers Viscient
Study Start Date:	May 18, 2011
Study Completion Date:	March 28, 2012
Inspector:	Daniel M. Myers U.S. EPA Office of Compliance, GLP Program

THIS REPORT PERTAINS TO THE AUDIT OF THE FOLLOWING ASPECTS OF THE STUDY:

AMPHIBIAN METAMORPHOSIS ASSY – APPENDIX D

I. SUMMARY OF AUDIT FINDINGS

This study was conducted after the effective date of the FIFRA GLP Standards regulations, 40 CFR Part 160 [Exhibit D-1]. The study report contained a GLP compliance statement signed by the sponsor, submitter and study director as required by § 160.12 [Exhibit D-1].

- No observed adverse findings.

II. CONDUCT OF THE AUDIT

This study audit was accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements and appropriate SOPs and the study protocol.

The following aspects of the study were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt and distribution and administration and chemical characterization.

Any issues were discussed with facility personnel, during the course of the inspection and/or during the exit conference.

III. STUDY AUDIT FINDINGS

- No observed adverse findings.

IV. EXHIBITS

Exhibit D-1 Final study report information pages including the Protocol cover page (5 pages)

V. INSPECTOR

Name: Daniel Myers
Affiliation: U.S. EPA Office of Compliance
GLP Program

Daniel Myers

5/30/2013
Date